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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Hiroyuki Takada

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EXAMINER

RAMDHANIE, BOBBY

ART UNIT

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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,231	Applicant(s) TAKADA ET AL.	
	Examiner BOBBY RAMDHANIE	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-18 and 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see Remarks, filed 04/08/2010, with respect to the rejection under Hiramatsu et al in view of Lee et al, have been fully considered and are persuasive. The rejection of 103(a) under Hiramatsu et al in view of Lee et al, has been withdrawn.
2. Applicant's arguments filed 04/08/2010, in respect to the rejection of 103(a) under Hiramatsu et al in view of Jenkins et al, have been fully considered but they are not persuasive. the following reasons are why:
3. Applicants argue that Hiramatsu et al in view of Jenkins et al does not disclose the alleged invention because Applicants interpret the Jenkins et al reference to only disclose that the projections 30 and channels 32 to be limited to at or near the bottom of the receptacle.
4. The Examiner respectfully disagrees.
5. As disclosed in Jenkins et al, "It should be appreciated that the sonication improving projections 30 may be disposed in any convenient orientation or at any convenient location within the container 10 (See Column 4 lines 43-47)."
6. Applicants also argue that "Providing projections 30 and/or channels 32 at the same location as the pad would interfere with the pad 114, preventing the device from working as originally intended (See Remarks Page 6)." This statement has been found to be unpersuasive because Applicant has not shown this using any scientific statistical

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data or a working model of the Jenkins et al invention with the projections and channels at the top and demonstrating that this working model does not work.

7. Applicants state in the Remarks that, "Claim 11 has been revised to include all of the features of claim 25. Claim 25 has been canceled to track with claim 11. Claim 11 further is supported by, for example, Figs, 3-5 and 10B. There is no new matter."

8. The Examiner respectfully disagrees. A negative limitation was further added to the amendment of Claim 11. This negative limitation was not in Claim 25 as stated in the Remarks. This new limitation introduces new matter.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 11-18 & 20-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

11. Applicants have amended claims 11-18 & 20-24 to incorporate the new limitation of "the adhering liquid moving groove being provided without a fillet, the adhering liquid moving groove having a lower end positioned below a surface of the liquid when the well contains a desired amount of the liquid."

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12. This new limitation neither has written support in the Specification nor is this negative limitation shown in the Figures 3-5, & 10B, as Applicants state on Page 5 of the Remarks filed on 04/08/2010. The Specification which describes the above Figures also does not support the new limitation.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 11-14, 16-18, 20-22, & 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over HIRAMATSU ET AL in view of JENKINS ET AL (US4847050)

16. Applicants' claims are toward a device.

17. Regarding Claims 11-14, 16-18, & 20-22, & 24, HIRAMATSU ET AL discloses the cartridge, comprising: A). A receptacle body, including an upper surface; a plurality of wells formed in the receptacle body, the plurality of wells including: at least one

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storage well, including an upper opening flush with the upper surface of the receptacle body, and a closed bottom for containing a liquid, and at least one reaction well including; an upper opening flush with the upper surface of the receptacle body, a closed bottom for providing a reacting field; wherein a closure is attached to the upper surface of the receptacle body for closing at least the upper opening of the storage well, and wherein at least one of the storage well and the reaction well (See Figure 1 Items 21-29 & A-C).

18. HIRAMATSU ET AL does not disclose that the reaction well includes an inner surface provided with an adhering liquid moving groove extending from the upper opening flush with the upper surface of the receptacle body to at an intermediate position short of the bottom of the receptacle body for downwardly moving the liquid which adheres on a peripheral portion of the upper opening of the well and on the closure by overcoming a surface tension of the adhering liquid, the adhering liquid moving groove being provided without a fillet, the adhering liquid moving groove having a lower end positioned below a surface of the liquid when the well contains a desired amount of the liquid.

19. JENKINS ET AL discloses a cartridge with A). At least one storage well including an upper opening and a closed bottom for containing a liquid (See Figure 1 Items 10 A-C); B). At least one reaction well including an upper opening and a closed bottom for providing a reacting field (See Figure 1 Items 10 A-C; and C). A closure for closing at least the upper opening of the storage well (See Column 2 lines 41-45, second sheet acts as a closure), wherein at least one of the storage well and the reaction well

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includes an inner surface wherein the inner wall provides an adhering liquid moving groove for downwardly moving the liquid which adheres on a peripheral portion of the upper opening of the well and on the closure by overcoming a surface tension of the adhering liquid and the adhering liquid moving groove being provided without a fillet, the adhering liquid moving groove having a lower end positioned below a surface of the liquid when the well contains a desired amount of the liquid (See Figure 3A-D & Column 4 line 58 to Column 5 line 37).

20. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wells of the cartridge of HIRAMATSU ET AL with the adhering liquid mover moving groove of JENKINS ET and extend it from the upper opening and terminating at an intermediate position short of the closed bottom because according to both JENKINS ET AL, these grooves assist in guiding of the circulating hydrating liquid (See JENKINS ET AL Column 4 lines 53-56) and JENKINS ET AL discloses the ability to position the grooves anywhere along the interior wall side (See Figure 2 Item 36 & See Column 4 lines 36-53).

21. Additional Disclosures Included: Claim 12: Wherein the liquid comprises at least one of a reagent, a diluent, and a cleaning solution (See HIRAMATSU ET AL Abstract, [0059], [0104], and [0105]); Claim 13: Wherein the liquid comprises a reagent (See HIRAMATSU ET AL Abstract, [0059], [0104], and [0105]); Claim 14: Wherein the reagent is necessary, for causing immune reaction (See HIRAMATSU ET AL [0001], [0059], [0104], and [0105]); Claim 16: Wherein the closure comprises a sheet that contacts an upper end of the adhering liquid moving groove (See HIRAMATSU ET AL

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Figure 3 Item 31 in view of JENKINS ET AL where the liquid adhering moving groove can be positioned at the top of the well or is integrated to be at the top of the well); Claim 17: Wherein there are a plurality of storage wells, the sheet collectively covering the upper openings of the storage wells (See Jenkins et al; cover sheets & HIRAMATSU ET AL Figure 3 Item 31); Claim 18: Wherein the sheet covers the upper openings of at least two wells including the storage well (See Jenkins et al; cover sheets & HIRAMATSU ET AL Figure 3 Item 31); Claim 20: The adhering liquid moving groove is rectangular or round in section See JENKINS ET AL Figures 3A-D); Claim 21: The adhering liquid moving groove is V-shaped in section (See JENKINS ET AL Figure 3B grooves are V-shaped); Claim 22: The adhering liquid moving groove extends linearly and vertically (See JENKINS ET AL Figure 3C); and Claim 24: The adhering liquid moving groove including an upper end that contacts the closure (See HIRAMATSU ET AL Figure 3 Item 31 in view of JENKINS ET AL where the liquid adhering moving groove can be positioned at the top of the well or is integrated to be at the top of the well).

22. Regarding Claim 23, the combination of HIRAMATSU ET AL with JENKINS ET AL discloses the cartridge according to claim 11, except wherein the adhering liquid moving groove mover extends spirally. JENKINS ET AL discloses many different shapes and configurations (See JENKINS ET AL Figures 3A-D).

23. It would have been an obvious matter of design choice to modify the structure to be a spiral, since applicant has not disclosed that the spiral shape solves any

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stated problem or is for any particular purpose and it appears that the invention would perform equally well with other shapes and configurations.

24. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over HIRAMATSU ET AL in view of JENKINS ET AL (US4847050) and in further view of Okubo et al.

25. Applicants' claims are toward a device.

26. Regarding Claim 15, the combination of HIRAMATSU ET AL and JENKINS ET AL discloses cartridge according to Claim 14, except wherein the reagent is made by dispersing an immune reactant, which reacts selectively with a specific component in a sample, in liquid as supported on solid particles. Okubo et al discloses a cartridge with this feature (See the machine English translation of JP2001318101; See Claim 9; microparticle & See [0003]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify either combinations of HIRAMATSU ET AL and JENKINS ET AL, with Okubo et al, because according to Okubo et al, this immunoassay method which consists of anchoring the antibody or antigen to a substrate such as a microparticle is widely used as a measuring method with simple operation.

Telephonic Inquiries

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

28. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BOBBY RAMDHANIE whose telephone number is (571)270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. R./

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797